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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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GRUN, J	
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AUDLEY A CIAMPORCERO JR
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK NJ 08933

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/585,820	Applicant(s) MERCOLINO et al.
	Examiner James L. Grun, Ph.D.	Group Art Unit 1641

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-24* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-24* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. When formal drawings are submitted, the draftsperson will perform a review. Direct any inquiries concerning drawing review to the Drawing Review Branch at (703) 305-8404.

The disclosure is objected to because of the following informalities: at page 3, line 28, after "and", it is believed that --3,666,421-- was intended. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant desires simultaneous determination of forward and reverse ABO blood group. This is exemplified by reacting a blood sample with differently labelled anti-A antibodies and B-bearing cells, or with differently labelled anti-B antibodies and A-bearing cells. However, absent further description and guidance from Applicant, one would not be able to make and use the invention as instantly claimed in which all of anti-A antibodies, A-bearing cells, anti-B antibodies, and B-bearing cells are reacted with the same sample because all samples tested would have a reaction between the specific binding pairs A/anti-A and B/anti-B. Moreover, reacting different sample fractions with the combination of anti-A antibodies and anti-B antibodies (forward), or with the combination of A-bearing cells and B-bearing cells (reverse) does not allow one to accomplish simultaneous determination of forward and reverse ABO blood group as desired.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant teaches the use of labelled reagent red cells bearing antigens (see e.g., page

6, lines 14-15, and page 10, lines 22-28) and does not teach cells bearing labelled antigens as is instantly claimed. Absent further description from Applicant, one would not be guided to, and would not be assured of the ability to, label the antigens with the labels as instantly disclosed and claimed. Moreover, Applicant provides no guidance to fluorochromes as antigen as instantly recited in claim 7.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-7, 11-12, 14-17 and 19-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-2, 4-7, 14-17, and 19-24, the interrelationships of the sample or samples are not clear.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as

to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance: claims 6 and 7 recite the broad recitation "phycobiliproteins", and these claims also recite "including phycoerythrin" which is the narrower statement of the range/limitation; and, claims 11-12 recite the broad recitations "reactive dyes", "lipophilic dyes", or "monoclonal antibodies", and these claims also recite "e.g., fluorescein...", "e.g., merocyanine...", or "e.g., anti-glycophorin-PE..." which are, respectively, the narrower statements of the range/limitation.

In claims 6-7, the abbreviations "FITC", "BODIPY", "AMCA", and "TRITC" should be defined for clarity. It is not clear for what the indocarbocyanine is "reactive" and, thus, it is not clear what is encompassed.

In claims 11-12, the abbreviations "PE" and "$DiIC_{18}(3)$-DS" should be defined for clarity. It is not clear for what the lipophilic dyes are "reactive" and, thus, it is not clear what is encompassed. In these claims, "the reactivity" lacks antecedent basis.

Claims 22-24 contain the trademark/trade name BIOVUE™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or

trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a cassette of unknown structure/limitation containing columns with added microparticle matrix for column agglutination and, accordingly, the identification/description is indefinite.

In claims 23-24, it is not clear how the system or reader are related to or further limit "visual analysis".

Claim 23 contains the trademark/trade name AUTOVUE™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an automated reader/imaging system of unknown structure/limitation and, accordingly, the identification/description is indefinite. Further, the recitations of "the...system" and "the agglutination result" lack antecedent basis.

Claim 24 contains the trademark/trade name BIOVUE™ Reader 2. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product,

the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an automated reader/imaging system of unknown structure/limitation and, accordingly, the identification/description is indefinite. Further, the recitations of "the...Reader 2" and "the agglutination result" lack antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 14-20 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ullman (U.S. Pat. No. 4,584,277).

Ullman teaches fluorescently labelled anti-blood group antigen antibodies and fluorescently labelled erythrocytes having blood group antigens thereon added simultaneously or sequentially to

a sample of whole blood for multiparameter analysis of ABO blood type and isoantibodies (i.e. reverse blood typing) (see e.g. col. 3-4). A variety of combinations of parameters and suitable reagents are taught (see e.g. col. 3, Table 1). Suitable fluorescent labels are taught (e.g. col. 8-9). Inherently, antibodies of the ABO system are generally IgM.

Claims 16, 17, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Yves [Lapierre] et al (U.S. Pat. No. 5,338,689).

The reference teaches a column agglutination assay and device for determination of agglutinated reactants, especially red blood cells in forward and reverse blood typing assays (see e.g. Figs. 5-7). The blood typing assays require the addition and reaction of reagents as instantly claimed (see e.g. col. 4-6). The reference teaches that the solid carrier particles, e.g. erythrocytes, can be naturally colored or can be stained or labelled (see e.g. col. 2).

Claims 16, 17, and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chachowski et al (U.S. Pat. No. 5,552,064).

Chachowski et al teach a column agglutination assay and device (see e.g. col. 4-5) for determination of agglutinated reactants, especially red blood cells in forward and reverse blood typing assays (see e.g. col. 6-8). Inherently the blood typing assays require the addition and reaction of reagents as instantly claimed. The reference teaches that erythrocytes are naturally stained by their hemoglobin content (see e.g. col. 7).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-12 and 14-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ullman (U.S. Pat. No. 4,584,277) in view of Vorpahl et al (U.S. Pat. No. 5,071,774) and Chang et al (U.S. Pat. No. 4,748,129).

The teachings of Ullman are as set forth above and differ from the invention as instantly disclosed in not teaching agglutination of the erythrocytes and in not teaching fluorophore incorporated into the erythrocytes.

Vorpahl et al teach that determination of the agglutination of two sets of red blood cells can be used for determination of the presence of an agglutinating agent for one or both of the red blood cell sets (see e.g. col. 9). As in Ullman, combined addition of means for separately agglutinating two sets of red blood cells (e.g., anti-blood group antigen antibodies) along with the two sets of

erythrocytes (e.g. erythrocytes having blood group antigens thereon), at least one of the sets being labelled with a fluorophore such that the sets are separately detectable and distinguishable, to a sample is used in the method.

Chang et al teach the addition of a fluorescent agent capable of incorporation into a cell as a means of labelling erythrocytes for agglutination assays. Suitable fluorescent agents are taught (e.g. col. 4-7).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have used agglutinating anti-blood group antigen antibodies, as in Vorpahl et al, in the method of Ullman because one would have expected such antibodies to perform their expected and desired binding function in the assay of Ullman, as modified, and would not have expected such agglutinating antibodies to interfere in the determination because Vorpahl et al teach that agglutination is desirable and detectable with a method of like design. It would have been further obvious to have used a fluorescent agent capable of incorporation into a cell, as in Chang et al, as the means of labelling erythrocytes in Ullman because Ullman requires fluorescently labelled erythrocytes, Chang et al teach incorporated labelling as particularly useful in assays typing red blood cells, and one would have expected the incorporated labelling to function as desired for providing fluorescently labelled cells in Ullman, as modified. The use of any known and available fluorescent agent capable of incorporation into a cell having the properties preferred by Chang et al would have been an obvious substitution to one of ordinary skill in the art. It would have been further obvious

to formulate the reagents of Ullman, as modified, into a kit since that is conventional for convenience, economy, and reproducibility.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claims 16, 17, and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chachowski et al (U.S. Pat. No. 5,552,064) in view of Shen et al (U.S. Pat. No. 5,594,808).

The teachings of Chachowski et al are as set forth previously in this Office action and differ from the invention as instantly claimed in not teaching an apparatus for interpretation of agglutination results.

Shen et al teach an apparatus and method for classifying agglutination reactions in column agglutination devices.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have used the device of Shen et al for interpreting the results of Chachowski et al because of the express suggestion in Shen et al to do so.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The disclosure of Ullman (U.S. Pat. No. 4,713,348) is essentially identical to the disclosure of Ullman (U.S. Pat. No. 4,584,277).

Vyas et al (U.S. Pat. No. 5,776,711) teach a simultaneous blood typing/antibody screening method using flow cytometry.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to James L. Grun, Ph.D., Technology Center 1600, Group 1640, Art Unit 1641, whose telephone number is (703) 308-3980. The Examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399. The fax phone numbers for official communications to Group 1640 are (703) 305-3014 or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

James L. Grun, Ph.D.
February 2, 2001

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641